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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,060	01/10/2006	Naoto Hagiwara	284206US0PCT	3962
22850 7590 05/01/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER STAPLES, MARK	
			ART UNIT 1637	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			NOTIFICATION DATE 05/01/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 05/01/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/564,060	Applicant(s) HAGIWARA, NAOTO	
	Examiner Mark Staples	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/02/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 01/10/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-8 and 10-20 in the reply filed on 02/02/2007 is acknowledged. The traversal is on the ground(s) that application was filed as a national stage application. This is found persuasive as first of invention of each group under PCT rules is to be examined.

Claims 1-20 will be fully examined for patentability.

Priority

2. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

No English translation has been provided for Japan 2003-273430 application filed on 07/11/2003. The effective filing date for the instant application is 07/12/2004.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other

information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the results of detection in Figure 9, due to the poor quality of this figure, as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

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applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "the flow channel comprises the denaturation region and the regeneration region alternately". At least two different interpretations can be made: (1) the flow channel has either the denaturation region or the regeneration region, or (2) the flow channel has a denaturation region followed by a regeneration region.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 9, 11, 12, 14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Misako et al. (JP 2003-174900, published on 24.06.2003).

Misako et al. teach a nucleic acid amplification device comprising a first treatment chamber wherein a sample solution containing nucleic acid is heated and the nucleic acid therein is denatured into single strands, a second treatment chamber wherein the single-stranded nucleic acid obtained in the aforementioned first treatment chamber is annealed to a primer, and a third treatment chamber wherein DNA polymerase acts upon the nucleic acid obtained in the second treatment chamber and a lengthening reaction is performed thereby. In addition, Misako et al. describe the immobilization of the DNA polymerase, a nucleic acid synthetase, in the reaction vessel and the formation of a circulatory flow route containing the aforementioned first, second, and third treatment chambers in the device (see especially Claims 11 to 13; Figure 3). The "first treatment chamber" of Misako et al. is equivalent to the "denaturation region" of this application, and the "second treatment chamber" and "third treatment chamber" of document 1 are formed in succession and are equivalent to the "regeneration region" of the present application.

Regarding claim 4, it is inherent in the teaching of Misako et al. that polymerase is immobilized on an inner wall surface as the DNA polymerase is fixed in the reactor where the amplification takes place. The amplification components being fluid must be contained within the reactor (see especially Claims 11 to 13; paragraph 0023; and Figure 3).

Further regarding claims 5, 12, 14, and 19; claims 5, 12, and 14 are given the first interpretation noted above, which is that the flow channel can comprise either the denaturation region or the regeneration region. And as noted above, Misako et al.

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teach that the flow channel can comprise either the denaturation region or the regeneration region.

Furthermore, the PCR method wherein a heating cycle is performed between two temperatures by performing annealing and a lengthening reaction simultaneously at the same temperature was widely known technology at the time this application was filed (as evidenced by *Biotechniques*, 1993, 14(3), p. 390-4, cited on the Information Disclosure Statement, IDS).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 10, 13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misako et al. as applied to claims 1 and 2 above, and further in view of Moses et al. (1994).

Here claims 13 is given the first interpretation noted above, which is that the flow channel can comprise either the denaturation region or the regeneration region.

Misako et al. teach as noted above.

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Regarding claims 3 and 10, Misako et al. teach immobilizing a polymerase but do not specifically teach a immobilizing a polymerase or other nucleic acid synthetase on beads.

Regarding claims 13 and as noted above, Misako et al. teach that the flow channel can comprise either the denaturation region or the regeneration region.

Regarding claims 20 and as noted above, Misako et al. teach that the flow channel can comprise the denaturation region and the regeneration region.

Regarding claims 3 and 10, Moses et al. teach DNA polymerase, a type of synthetase, bound to beads which fill a column (entire reference, especially Figure 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Misako et al. by immobilizing a nucleic acid synthetase on beads as suggested by Moses et al. with a reasonable expectation of success. The motivation to do so is provided by Moses et al. who teach that the polymerase can be bound to beads, retain activity and that reagents can be passed over the beads. Further motivation is provided by Misako et al. teach that immobilized polymerase can be used to amplify DNA. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

8. Claims 5, 12, and 14 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Misako et al. as applied to claims 1, 2, and 4 above, and further in view of Hideo et al. (JP 6-30776 A, published on 08.02.1994).

The second interpretation of claim 5 is used here, that is, that denaturation and regeneration regions alternate each other in the flow channel.

Misako et al. teach as noted above.

Misako et al. teach denaturation and regeneration regions but do not teach where they alternate each other in the flow channel.

Hideo et al. teach where denaturation and regeneration regions alternate each other in the flow channel (especially Figures 1 and 2 and where in Figure 2 the coil involves more than one loop and thus inherently alternates the denaturation and regeneration regions. It is further noted that Figure 2 of Hideo et al. is the same construction as Figure 5 of the instant application and they achieve the same thing, alternating regions of denaturation and regeneration).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Misako et al. alternating regions of denaturation and regeneration as suggested by Hideo et al.. with a reasonable expectation of success. The motivation to do so is provided by Hideo et al. who teach that coli can be used to have flow going through alternating regions of denaturation and regeneration. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

9. Claim 13 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Misako et al. and Moses et al. as applied to claims 1 and 3 above, and further in view of Hideo et al. (JP 6-30776 A, published on 08.02.1994).

The second interpretation of claim 13 is used here, that is, that denaturation and regeneration regions alternate each other in the flow channel.

Misako et al. and Moses et al. teach as noted above.

Misako et al. teach denaturation and regeneration regions but do not teach where they alternate each other in the flow channel.

Hideo et al. teach where denaturation and regeneration regions alternate each other in the flow channel (especially Figures 1 and 2 and where in Figure 2 the coil involves more than one loop and thus inherently alternates the denaturation and regeneration regions. It is further noted that Figure 2 of Hideo et al. is the same construction as Figure 5 of the instant application and they achieve the same thing, alternating regions of denaturation and regeneration).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Misako et al. alternating regions of denaturation and regeneration as suggested by Hideo et al.. with a reasonable expectation of success. The motivation to do so is provided by Hideo et al. who teach that coli can be used to have flow going through alternating regions of denaturation and regeneration. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

10. Claims 6, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misako et al as applied to claim 1-3 above, and further in view of Schelper et al. (1997).

Misako et al. teach as noted above.

Misako et al. teach a nucleic acid synthetase but do not specifically teach one which has a temperature optimum between 30 to 40°C.

Regarding claims 6 and 15-19, Schelper et al. teach: "The temperature optimum of *C. symbiosum* polymerase [a type of nucleic acid synthetase] in our activity assay was found to be between 38°C and 42°C" which overlaps the 30 to 40°C range of the instant claims.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Misako et al. by using a polymerase with a temperature optimum in the range of 38 to 40°C as suggested by Schelper et al. with a reasonable expectation of success. The motivation to do so is provided by Schelper et al. who teach nucleic acid amplification can be accomplished with by a polymerase with a temperature optimum in the range of 38 to 40°C. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Misako et al. as applied to claim 1 above, and further in view of Southgate et al. (US Patent No: 5,863,801, issued 1999).

Misako et al. teach as noted above.

Misako et al. teach flow device but do not specifically teach a flow device in which the flow direction can be reversed.

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Southgate et al. teach a device with reverse flow (see paragraph 114 which describes Figure 6).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Misako et al. by incorporating reverse flow as suggested by Southgate et al. with a reasonable expectation of success. The motivation to do so is provided by Southgate et al. who teach reversing flow in a device can be used to suspend beads in that device to allow better mixing of the sample with beads. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Misako et al. and Moses et al. as applied to claims 1 and 3 above, and further in view of Schelper et al. (1997).

Misako et al. and Moses et al. teach as noted above.

Misako et al. and Moses et al. teach a nucleic acid synthetase but do not specifically teach one which has a temperature optimum between 30 to 40°C.

Regarding claims 6 and 15-19, Schelper et al. teach: "The temperature optimum of *C. symbiosum* polymerase [a type of nucleic acid synthetase] in our activity assay was found to be between 38°C and 42°C" which overlaps the 30 to 40°C range of the instant claims.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Misako et al. and Moses et

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al. by using a polymerase with a temperature optimum in the range of 38 to 40°C as suggested by Schelper et al. with a reasonable expectation of success. The motivation to do so is provided by Schelper et al. who teach nucleic acid amplification can be accomplished with by a polymerase with a temperature optimum in the range of 38 to 40°C. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

13. No claim is free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
April 25, 2007

MS


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

4/26/07